

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicants: Vargas, Jaime; et. al.  
Assignee: Cardica, Inc.  
Title: Method for Cutting Tissue  
Serial No.: 10/698,575                      Filing Date: October 31, 2003  
Examiner: Truong, Kevin T.              Group Art Unit: 3734  
Docket No.: 146

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August 6, 2007

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Commissioner for Patents  
P. O. Box 1450  
Alexandria, VA 22313-1450

**APPEAL BRIEF UNDER 37 CFR §41.37**

This Appeal Brief is prepared and submitted pursuant to the Notice of Appeal filed in this case on June 11, 2007.

**I. REAL PARTY IN INTEREST**

The real party in interest is the assignee, Cardica, Inc., as named in the caption above.

**II. RELATED APPEALS AND INTERFERENCES**

No pending appeals, interferences or other judicial proceedings, or prior interferences or other judicial proceedings, are known to Appellant, Appellant's legal representative, or assignee which may be related to, directly affect or be directly affected by, or have a bearing on the decision by the Board of Patent Appeals in this appeal. No court or Board has rendered a decision pertaining to this patent application, and no such decisions can be provided in the Related Proceedings Appendix.

**III. STATUS OF CLAIMS**

Claims 8-21 and 23 stand finally rejected. These claims are set forth in the appendix attached hereto.

Claims 1-7 and 22 have been canceled, and as a result are not set forth in the appendix attached hereto.

#### **IV. STATUS OF AMENDMENTS**

No amendments were filed after final rejection or are currently pending in this case.

#### **V. SUMMARY OF CLAIMED SUBJECT MATTER**

##### **A. Claim 8**

Claim 8 is directed to a method for making an opening in a vessel (170), where that method comprises piercing the wall of the vessel (170) with a piercing element (14); retracting the piercing element (14) at least partially into a tube (16) having a lumen; and moving the piercing element (14) away from the longitudinal centerline of the tube (16), after that retracting.<sup>1</sup> Claims 9-15 depend from independent claim 8, and thus add additional limitations to those present in independent claim 8.

##### **B. Claim 16**

Claim 16 is directed to a method for making an opening in the wall of a hollow tissue structure (170), where that method comprises piercing the wall of the hollow tissue structure (170), at a location in the wall through which fluid previously had been substantially prevented from escaping, with a piercing element (14) to create an opening (184) therethrough; retracting the piercing element (14) toward an opening (26) in a body (16) to cut a tissue plug (180) from the wall of the hollow tissue structure (170); capturing the tissue plug (180) with the piercing element (14); and moving the piercing element (14) away from the longitudinal centerline of the body (16) after that capturing.<sup>2</sup> Claims 17-21 and 23 depend from independent claim 16, and thus add additional limitations to those present in independent claim 16.

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<sup>1</sup> E.g., Specification, page 4, lines 13-17; page 6, line 19 through page 9, line 9; page 12, lines 20-23; page 13, lines 4-5; Figures 1-5, 25-28 (exemplary reference characters indicated in text above).

<sup>2</sup> E.g., Specification, page 4, lines 13-17; page 6, line 19 through page 9, line 9; page 12, lines 20-23; page 13, lines 4-5; Figures 1-5, 25-28 (exemplary reference characters indicated in text above).

## **VI. GROUNDINGS OF REJECTION TO BE REVIEWED ON APPEAL**

### **A. Claims 8-15**

Independent claim 8 stands finally rejected under 35 U.S.C. §102(e) as being anticipated by U.S. Patent No. 6,699,256 to Logan et. al. (“Logan”). Dependent claims 9-15 also stand rejected under Logan.

### **B. Claims 16-21, 23**

Independent claim 16 stands finally rejected under 35 U.S.C. §102(e) as being anticipated by U.S. Patent No. 6,699,256 to Logan et. al. (“Logan”). Dependent claims 17-21 and 23 also stand rejected under Logan.

## **VII. ARGUMENT**

### **A. The Cited Art Does Not Anticipate the Claims**

The MPEP sets forth the legal standard of anticipation under 35 U.S.C. §102: “A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.”<sup>3</sup> (emphasis added).

#### **1. Claims 8-15**

Claim 8 claims “[a] method for making an opening in a vessel, comprising: piercing the wall of the vessel with a piercing element; retracting said piercing element at least partially into a tube having a lumen; and moving said piercing element away from the longitudinal centerline of said tube, after said retracting.”

In contrast, U.S. Pat. No. 6,699,256 to Logan et. al. (“Logan”) does not expressly or inherently describe “moving said piercing element away from the longitudinal centerline of said tube, after said retracting.” The Final Action of April 3, 2007 (“Final Action”) identifies the stylet 322 of Logan as analogous to the claimed “piercing element.”<sup>4</sup> The stylet 322 is movable linearly along the longitudinal centerline of a tube.<sup>5</sup> After the stylet 322 punctures the wall of the vessel, it is simply retracted “proximally” into a tubular coring tip 324.<sup>6</sup> Nowhere does Logan describe motion of the

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<sup>3</sup> MPEP 2131 (quoting *Verdegaal Brothers v. Union Oil of California*, 814 F.2d 628, 631 (Fed. Cir. 1987)).

<sup>4</sup> Final Action, page 2.

<sup>5</sup> Logan; e.g., Figures 21-23.

<sup>6</sup> Logan; col. 13, lines 22-30; Figure 23.

stylet 322 “away from the longitudinal centerline of [a] tube,” either before or after the stylet 322 is retracted; the motion of the stylet 322 is simply linear and translational. Thus, Logan does not and cannot describe the claimed “moving said piercing element away from the longitudinal centerline of said tube, after said retracting.”

The Final Action advances, for the first time, the ground of rejection “that the piercing element 322 as shown in Logan et al is clearly capable of being moved away from the longitudinal centerline of the trocar (324) after retracting...when piercing element (322) [is] detached from trocar (324).”<sup>7</sup> However, this ground of rejection rests solely on speculation, not on any disclosure within Logan. The Office Action admits as much by failing to cite a single line of text or a single figure in Logan that discloses the purported detachability of a piercing element 322 from a trocar 324. Nowhere does Logan describe or even suggest that the piercing element 322 is detachable from the trocar 324 after cutting a tissue plug from a vessel wall. Indeed, to the extent Logan discloses the handling of a tissue plug at all, it states that “barbs 448 and the coring tip 444 retain the tissue [of the plug] therebetween,”<sup>8</sup> and that “[b]arbs 526 retain the plug 42 inside the coring tip 530 and prevent the plug 42 from entering the bloodstream (FIG. 29).”<sup>9</sup> A piercing element 322 cannot at once retain the plug 42 inside the coring tip 530 of the trocar 324 and be detached from the trocar 324. Thus, not only does Logan not expressly or inherently describe removing a piercing element from a trocar under 35 U.S.C. §102, it also teaches away from doing so under 35 U.S.C. §103.

As a result, Logan does not expressly or inherently describe each and every element of claim 8, and claim 8 is believed to be in condition for allowance. Claims 9-15 depend from claim 8, and are thus believed to be in condition for allowance as well under MPEP 608.01(n)(III).

With regard to dependent claim 12, Logan nowhere describes the claimed “pivoting said piercing element,” and the Final Action does not contend that Logan does so. Nowhere does the Final Action identify any such description within Logan. By failing to identify any description within Logan that anticipates claim 12, but still rejecting claim 12 as anticipated by Logan, the rejection of claim 12 in the Final Action violated the Administrative Procedure Act, which requires federal administrative agencies such as the Patent and Trademark Office must support their decisions with “substantial evidence” for those decisions to be valid.<sup>10</sup> Further, the Final Action ignores the

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<sup>7</sup> Final Action, page 3. (emphasis added).

<sup>8</sup> Logan; col. 12, lines 13-14.

<sup>9</sup> *Id.*; col. 14, lines 7-9 (emphasis added); Figure 29.

<sup>10</sup> 5 U.S.C. § 706; *Dickinson v. Zurko*, 1999 U.S. Lexis 4004, \*24; 527 U.S. 150 (1999) (citing *SEC v. Chenery Corp.*, 318 U.S. 80, 89-93(1943)).

portion of the Response to Office Action of January 10, 2007, which clearly states that Logan does not describe the “pivoting said piercing element” limitation.

With regard to dependent claim 13, Logan nowhere describes the claimed “storing said piercing element adjacent to said tube,” and the Office Action does not contend that Logan does so. Nowhere does the Final Action identify any such description within Logan. By failing to identify any description within Logan that anticipates claim 13, but still rejecting claim 13 as anticipated by Logan, the rejection of claim 13 in the Final Action violated the Administrative Procedure Act, which requires federal administrative agencies such as the Patent and Trademark Office must support their decisions with “substantial evidence” for those decisions to be valid.<sup>11</sup> Further, the Final Action ignores the portion of the Response to Office Action of January 10, 2007, which clearly states that Logan does not describe the “storing said piercing element adjacent to said tube” limitation.

## 2. Claims 16-21, 23

Claim 16 claims “[a] method for making an opening in the wall of a hollow tissue structure, comprising: piercing the wall of the hollow tissue structure, at a location in the wall through which fluid previously had been substantially prevented from escaping, with a piercing element to create an opening therethrough; retracting the piercing element toward an opening in a body to cut a tissue plug from the wall of the hollow tissue structure; capturing the tissue plug with said piercing element; and moving said piercing element away from the longitudinal centerline of said body after said capturing.”

The discussion above with regard to claim 8 applies equally here. Nowhere does Logan describe the claimed “moving said piercing element away from the longitudinal centerline of said body after said capturing.” As a result, Logan does not expressly or inherently describe each and every element of claim 16, and Applicants believe claim 16 is in condition for allowance. Claims 17-21 and 23 depend from claim 16, and are thus believed to be in condition for allowance as well under MPEP 608.01(n)(III).

With regard to dependent claim 23, Logan nowhere describes the claimed “side opening,” and the Office Action does not contend that Logan does so. Nowhere does the Final Action identify any such description within Logan. By failing to identify any description within Logan that anticipates claim 23, but still rejecting claim 23 as anticipated by Logan, the rejection of claim 23 in the Final

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<sup>11</sup> 5 U.S.C. § 706; *Dickinson v. Zurko*, 1999 U.S. Lexis 4004, \*24; 527 U.S. 150 (1999) (citing *SEC v. Chenery Corp.*, 318 U.S. 80, 89-93(1943)).

Action violated the Administrative Procedure Act, which requires federal administrative agencies such as the Patent and Trademark Office must support their decisions with “substantial evidence” for those decisions to be valid.<sup>12</sup> Further, the Final Action ignores the portion of the Response to Office Action of January 10, 2007, which clearly states that Logan does not describe the “side opening” limitation.

## **VII. CONCLUSION**

For the above reasons, Applicants respectfully submit that the Final Action’s rejection of pending claims 8-21 and 23 was unfounded. Accordingly, Applicants request that the rejection of those claims be reversed and that those claims be allowed, or in the alternative that this case be transmitted to the Board of Patent Appeals and Interferences for resolution.

Respectfully submitted,

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<sup>12</sup> *Id.*

## **APPENDIX 1 -CLAIMS**

8. A method for making an opening in a vessel, comprising:
  - piercing the wall of the vessel with a piercing element;
  - retracting said piercing element at least partially into a tube having a lumen; and
  - moving said piercing element away from the longitudinal centerline of said tube, after said retracting.
9. The method of claim 8, wherein said moving includes moving said piercing element through an opening in a side wall of said tube.
10. The method of claim 9, wherein a member is attached to said piercing element and extends through said opening; and wherein said moving includes applying force to said member.
11. The method of claim 9, wherein said moving includes separating said piercing element from said tube.
12. The method of claim 9, wherein said moving comprises pivoting said piercing element at least partially through said opening.
13. The method of claim 9, further comprising storing said piercing element adjacent to said tube.
14. The method of claim 8, wherein said retracting cuts a tissue plug from the wall of the vessel.
15. The method of claim 14, further comprising retaining the tissue plug with said piercing element.
16. A method for making an opening in the wall of a hollow tissue structure, comprising:
  - piercing the wall of the hollow tissue structure, at a location in the wall through which fluid previously had been substantially prevented from escaping, with a piercing element to create an opening therethrough;
  - retracting the piercing element toward an opening in a body to cut a tissue plug from the wall of the hollow tissue structure;
  - capturing the tissue plug with said piercing element; and

moving said piercing element away from the longitudinal centerline of said body after said capturing.

17. The method of claim 16, wherein said body is a tube.

18. The method of claim 16 wherein said opening in said body has a cutting edge defined thereon.

19. The method of claim 16, wherein said piercing element includes a pointed tip and an anvil surface proximal to said pointed tip, and wherein said retracting moves said anvil surface toward said opening in said body to cut the tissue plug.

20. The method of claim 16, wherein said piercing is performed by urging said piercing element distally with spring force.

21. The method of claim 16, wherein said piercing is performed by manually advancing said piercing element in the distal direction.

23. The method of claim 16, wherein said body includes a side opening defined therein; and wherein said moving is through said side opening.



## **APPENDIX 2 – EVIDENCE APPENDIX**

None.

**APPENDIX 3 – RELATED PROCEEDINGS APPENDIX**

None.